

In re: Robert D. Black et al.  
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### REMARKS

This Amendment is submitted in response to the Office Action dated March 31, 2003 ("the Action"). Claims 1-68 are pending in the application. Claims 23 and 34 are stated to recite allowable subject matter. Claims 1-22, 24-33 and 35-68 stand rejected under 35 USC §103. Applicants respectfully disagree and will address the rejections below.

#### I. Allowable Subject Matter

Applicants acknowledge with appreciation the Examiners statement that Claims 23 and 34 recite allowable subject matter. Claims 23 and 34 have been amended hereinabove to be placed in independent form. Applicants note that Claim 23 has been written so as to exclude (not incorporate) the passive feature of the sensor or that the wireless reader powers the sensor as recited in independent Claim 21) in order to broaden the scope of this claim.

Applicants note for the record that the term "single-use disposable" includes sensors that are used once for a radiation measurement, but remain on the package or item without providing further radiation monitoring (are not reused for another batch or item); however, the sensors may not be actually physically removed and/or "disposed" from the package or item. That is, the used sensor is disposable but need not be removed from the product or item and deposited into a waste receptacle after its intended radiation measurement use.

#### II. The Cited Prior Art

Claims 1-22, 24-33 and 35-68 are rejected as being obvious over U.S. Patent No. 6,429,444 to Korenev et al. ("Korenev") in view of U.S. Patent No. 6,165,155 to Jacobsen et al. ("Jacobsen") or other secondary references. Applicants respectfully disagree.

#### Wireless Transmission

Korenev proposes a real-time electron beam radiation monitoring system. The system proposed by Korenev employs a conveyor system with arrays of fixed sensors spaced in fixed spatial alignment and position (with respect to the conveyor belt or item). The array of sensors measure radiation as it enters and exits the packages of items to determine a dose measurement of the items in the package (see col. 3, lines 20 et seq.). Korenev also proposes

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that the array of detectors can be mounted on the leading or trailing edge of the items to move with the items at col. 4, lines 61-65. Notably, however, Korenev fails to teach, *inter alia*, a wireless transmission or radiation data from the sensor arrays. The Action concedes this omission but states that Jacobsen teaches this feature. Applicants again respectfully disagree.

Jacobsen is directed to an electronically controlled drug system and is not directed to measuring radiation at all. One of skill in the art would not have combined Jacobsen with Korenev to yield the claimed invention in light of the harsh or severe operating environment of sterilization radiation systems. However, Applicants respectfully invite the Examiner to cite the passages relied on in Jacobsen in support of the position in the Action.

The device of Jacobsen is not exposed to harsh (radiation exposure) environments and the control pad of Figure 2 in Jacobsen would not operate to communicate with the remote processor contemplated by embodiments of the present invention. Further, the control pad includes a controller (which may wirelessly communicate with a remote computer) that is wired to the local drug delivery system and includes a battery and, hence, is not "passively" operated as contemplated by embodiments of the present invention.

In contrast, while not all embodiments of the present invention are operated passively, certain embodiments of the present invention contemplate sensor devices that can be passively operated (telemetrically powered) and/or configured to relay the dose data telemetrically. Thus, in particular embodiments, no battery or sensor-side power source or CPU is used, thereby decreasing the build cost of the units. The devices may be particularly suitable for assessing radiation doses in mass-production food or medical object irradiation facilities. In certain embodiments, the irradiation exposure may be between about .01-30kGy for food and 10-50kGy for medical devices (p.5, lines 1-5) and 10-75kGy for non-edible items (p. 20, line 19).

#### Dose Ranges

The Action states that Korenev fails to teach the dose range of Claims 13-15, 22, and 24 but then states that "this constitutes only a matter of design choice since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art." Applicants respectfully disagree.

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The dose ranges are not "mere design choices" but functional limitations of increasing severity in operational conditions that the system and sensor operate in, according to certain embodiments of the present invention. Thus, the operational ranges may be "design choices" but configuring the sensor and/or system to operate in these different harsh radiation exposure levels involves inventive efforts rather than "routine skill" and provides support of the inventiveness of these claims.

The Pending Claims Are Patentable Over The Cited References.

Applicants respectfully submit that the independent claims are patentable over the cited references. For example, Claim 1 recites a wireless transmission and disposable sensor body, independent Claim 21 recites the passive operation feature of the sensor, independent Claim 45 recites that the sensor is "inductively powered" and is configured to "wirelessly relay data", and independent Claim 59 recites that the sensor is a single use sensor.

Claims 26-32 have been amended in a non-narrowing manner and the amendments are not made to overcome rejections or cited prior art.

Applicants disagree with, but respectfully defer addressing, the rejections of the remaining cited references as applied against features recited in other (dependent) claims in the interest of brevity. However, Applicants submit that the dependent claims recite additional patentable features that will not be discussed herein in view of the patentability of the independent claims.

New Claims

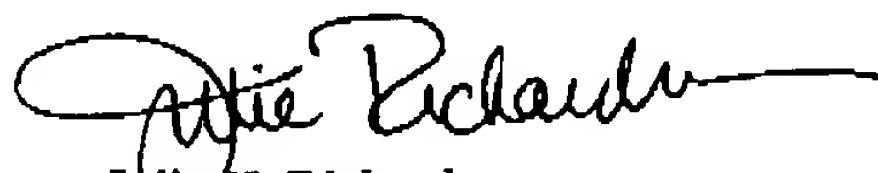
In order to form a more complete claim set, Applicants have added new dependent Claims 69-80 which features are supported by the application. Entry and consideration of same is respectfully requested.

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Conclusion

Applicants respectfully submit that the application is in condition for allowance which action is requested. The Examiner is invited to contact the undersigned to resolve any outstanding issues.

Respectfully submitted,



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Rosa Lee Brinson

Date of Signature: June 25, 2003